EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN,AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2875
THIS DOCUMENT RELATES TO: ALL ACTIONS	:	

DECLARATION OF [redacted]

I. BACKGROUND

1. [redacted]

2. [redacted]

[redacted]

3. [redacted]

4. I have reviewed the operative Master Economic Loss Class Action Complaint and am generally familiar with the allegations Plaintiffs make against Defendants in this MDL. I have also been provided with correspondence regarding discovery requests circulated between the parties that are pertinent to this Declaration.[1]

[1] Letter to Judge Schneider from Defendants providing their positions with respect to the topics on the agenda for the Case Management Conference with the Court on February 26, filed February 25, 2020 in *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, Case No. 1:19-md-02875 ("Defendants' Letter"); Letter to Judge Kugler and Judge Schneider from Plaintiffs in advance of the February 26, 2020 Case Management

5. [redacted]

6. This Declaration does not represent the totality of any opinions I may offer in this case at a later stage, especially given that I understand many Defendants have yet to produce any documents or information in discovery. I reserve the right to modify or supplement this Declaration if and when appropriate, particularly based upon additional information, evidence, and argument of which I am made aware subsequently.

II. SUMMARY OF PRELIMINARY OPINIONS ON DATA AVAILABILITY

7. Counsel for Plaintiffs have asked me to provide a brief, preliminary background about the types of data and information created and maintained in connection with how prescription drugs travel through the U.S. supply chain. I understand that the purpose for providing this information is to assist in constructing meaningful and informative discovery requests to Retail Pharmacy and Wholesaler Defendants[2] in order to obtain documents, data, and information pertinent to the issues in this case, and that these Defendants generally argue certain data is not available or is not needed by Plaintiffs. My preliminary opinions on data availability, as discussed more fully below, are as follows.

Conference, filed February 25, 2020 in *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, Case No. 1:19-md-02875.

[2] I understand the Retail Pharmacy Defendants include CVS Health, Wal-Mart, Walgreens, Rite Aid, Albertsons, Humana Pharmacy, OptumRx, Kroger, and Express Scripts. I understand the Wholesaler Defendants include AmerisourceBergen, Cardinal Health, and McKesson.

8. Data exist to trace and confirm the sale or purchase of valsartan and various valsartan containing drugs (collectively "VCDs") throughout the U.S. supply chain.

9. Commercial transfers of prescription drugs in the United States must be accompanied by certain objective information by law and industry practice. This information may be used to trace a particular type of prescription drug through the U.S. supply chain.

10. Under the Drug Supply Chain Security Act ("DSCSA") information that must be created or retained includes: product name; National Drug Code; container size; number of containers; lot number; date of transaction; date of shipment; and name and address of the entity transferring ownership and taking ownership of the product.[3]

11. Additionally, drug expiration dates are assigned to lots, appear on manufacturers' FDA-mandated drug labeling, and therefore are literally attached to a drug as it makes it way from a manufacturer, to a wholesaler and to the retail pharmacy. Thus, even in the absence of lot number, an expiration date is, standing alone, informative about the lot from which a drug came. For example, Cardinal Health includes expiration dates in the transaction records it provides to its pharmacy customers.[4]

12. Even if all of the following information is not provided at point-of-sale between defendants (e.g., assuming *arguendo* that a Wholesaler Defendant does not explicitly provide lot number to a Retail Pharmacy), entities in the drug supply chain maintain inventory systems (as a matter of best practices) that still contain the above information.

[3] As explained at ¶¶34-36 of this Declaration, under the DSCSA primary wholesalers are not required to include in the transaction history and transaction information some of this information. However, this does not mean they don't have this information in their technology and inventory systems.

[4] CardinalHealth, *Drug Transaction Data Reporting Under the Drug Supply Chain Security Act (DSCSA)*, accessed March 11, 2020 at https://www.cardinalhealth.com/content/dam/corp/web/documents/brochure/CardinalHealth-DrugTransactionDataUserGuide.pdf, at p. 4.

13. It is administratively feasible to use these and other data to identify objectively which consumers or third-party payors ("TPPs") paid for which VCDs, and, more importantly, to apportion the market of VCDs by each manufacturer, wholesaler, and retail pharmacy, over time. It would be much more challenging to apportion the total market of VCDs at issue in this litigation without these data from Retail Pharmacy and Wholesaler Defendants.

III. OVERVIEW OF THE DRUG SUPPLY CHAIN SECURITY ACT

14. The Drug Supply Chain Security Act ("DSCSA") was enacted in 2013, and requires prescription drug manufacturers, wholesalers, repackagers, and pharmacies to "[e]xchange information about a drug and who handled it each time it is sold in the U.S. market."[5]

15. The DSCSA was implemented as one part of the Drug Quality and Security Act (DQSA), aimed at addressing vulnerabilities in the drug supply chain, and facilitating tracing of certain prescription drugs in finished dosage form through the supply chain.[6]

16. It is worth noting that the DSCSA was implemented after a series of deadly incidents regarding drugs, including the tragic deaths of 81 people as a result of contaminated heparin API sourced from a Chinese drug manufacturer.[7]

17. While the DSCSA was enacted in 2013, in my experience, participants in the pharmaceutical supply chain (such as the wholesalers and retail pharmacies who are defendants in

[5] FDA, *Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act) Overview of Product Tracing Requirements*, September 2015, accessed March 4, 2020 at https://www.fda.gov/media/93779/download, at pp. 3, 5 and 8.
[6] U.S. Department of Health and Human Services, *Drug Supply Chain Security: Dispensers Received Most Tracing Information*, March 2018, accessed March 11, 2020 at https://oig.hhs.gov/oei/reports/oei-05-16-00550.pdf, at p. 2.
[7] Congressional hearing stating that the goal of the ultimate DSCSA was to create "a system by which we will be able to track drugs from the time they leave the manufacturing facility to the time they reach patients in the pharmacy, hospital, nursing home, or doctor's office" (U.S. Government Printing Office, House Hearing titled "The Heparin Disaster: Chinese Counterfeits and American Failures," April 29, 2008, accessed March 11, 2020 at https://www.govinfo.gov/content/pkg/CHRG-110hhrg53183/html/CHRG-110hhrg53183.htm).

this case) maintained similar information as a part of their ordinary course of business prior to the enactment of the DSCSA.

18. The DSCSA generally requires participants in the drug supply manufacturing chain (starting from the manufacturer, through the wholesaler, to the retail pharmacy) to retain, for every pharmaceutical drug transaction, the following information about that transaction: product name; National Drug Code; container size; number of containers; lot number; date of transaction; date of shipment; and name and address of the entity transferring ownership and taking ownership of the product.

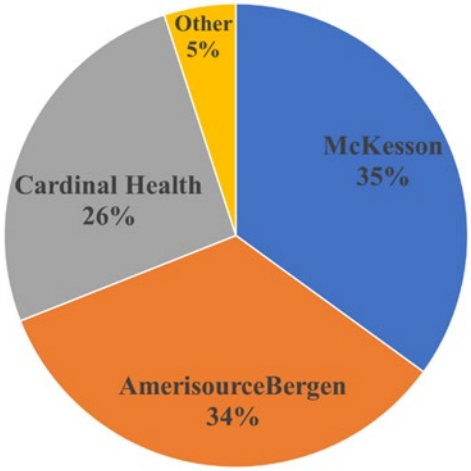
19. The DSCSA requires that this data be kept in a manner to allow these authorized participants to respond within 48 hours to requests from appropriate federal or state officials — in the event of a recall or for the purpose of investigating suspect product or an illegitimate product — for the transaction history of the pharmaceutical product. [8]

IV. DATA IS CONCENTRATED IN LARGE MARKET PARTICIPANTS

20. The supply chain for distribution of prescription drugs in the U.S. is highly concentrated. This means that data obtained from a relatively small number of market participants can provide detailed information about the large majority of VCD sales, transfers and prescription fills. Concentration is especially extreme among Wholesalers. As reflected in Figure 1 below, in 2018 the "big three" pharmaceutical wholesalers (McKesson, Cardinal Health, and AmerisourceBergen) together accounted for 95% of wholesale drug revenue in the United States.

[8] FDA, "Title II of the Drug Quality and Security Act," December 16, 2014, accessed March 11, 2020 at https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act.

Figure 1. U.S. Pharmaceutical Wholesalers Revenue Market Shares, 2018[9]



21. Retail distribution in the United States is concentrated in a relatively small number of large pharmacy chains. In 2019, Defendant pharmacies CVS Health Corporation, Walgreens Boots Alliance, Express Scripts, Inc., Walmart Stores, Inc., The Kroger Company, and Rite Aid Corporation captured 64% of U.S. prescription drug revenue.[10]

22. The entire process of reimbursing pharmacies and consumers for end-purchases depends upon the ability to know the precise drug and packaging that was dispensed, as well as the manufacturer of that drug. Making this system work has necessarily resulted in very high levels of data standardization in this industry. Although pharmacies maintain their own "pharmacy log" data reflecting dispensing, sales and return activity, the key elements are fundamentally similar.

[9] Fein, Adam J., "The Big Three Wholesalers: Revenues and Channel Share Up, Profits Down," *Drug Channels Institute*, October 2, 2019, accessed March 5, 2020 at https://www.drugchannels.net/2019/10/the-big-three-wholesalers-revenues-and.html.

[10] Fein, Adam J., "The Top 15 U.S. Pharmacies of 2019: Specialty Drugs Drive the Industry's Evolution," *Drug Channels Institute*, March 3, 2020, accessed March 5, 2020 at https://www.drugchannels.net/2020/03/the-top-15-us-pharmacies-of-2019.html.

23. Because pharmacies require similar information for their own tracking and inventory systems, and wholesalers sell to multiple pharmacy chains, the key elements are fundamentally the same.

24. Further, all pharmacies must use the basic data fields, definitions and formats provided in the Telecommunications Guidelines developed by the National Council for Prescription Drug Programs, the use of which was made mandatory in 2003 under regulations implementing the Health Insurance Portability and Accountability Act ("HIPAA").[11] Because of these HIPAA requirements, all of these inter-related systems (Manufacturers, Wholesalers, Retailers, and TPPs) use a common language to identify products.

V. TYPES OF AVAILABLE DATA

25. As a general matter, for Medicare and Medicaid compliance, pharmacies typically keep prescription records for ten years.[12] For instance, in its Pharmacy Manual, Walgreens Health Initiatives states the following: "Unless otherwise set forth in your Pharmacy Network Agreement with Walgreens Health Initiatives, records are required to be maintained and accessible for: (i) ten years following each year of the term in which the pharmacy provides services under the Pharmacy Network Agreement or longer as mandated by CMS (Centers for Medicare and Medicaid), for Medicare Part D; (ii) six years for the Medicare Drug Discount Card; and (iii) five years or per applicable federal or state law, whichever is longer, for any other Walgreens Health Initiatives' business records."[13] In discussing its Medicare Part D network standards, CVS says that each of

[11] Federal Register, August 17, 2000 (Volume 65, Number 160), at pp. 50311-50372; NCPDP, *Pharmacy: A Prescription for Improving the Healthcare System*, October 2009, accessed January 30, 2019 at https://www.ncpdp.org/NCPDP/media/pdf/wp/RxforImprovingHealthcare.pdf, at p. 14.
[12] CFR § 423.505(d).
[13] Walgreens, *Pharmacy Manual*, January 2011, accessed March 12, 2020, at http://www.walgreenshealth.com/pdf/forms/Revised_Pharmacy_Manual_2010_Revised_04072010.pdf, at p. 6.

its pharmacies is required to "maintain its books and records relating to [its] services, for a period of at least ten (10) years, or longer as otherwise required by law."[14] While I understand that the Retail Pharmacy and Wholesaler Defendants have not yet produced their applicable records retention policies, it is unlikely that their policies would call for shorter record retention than Medicare and Medicaid requirements, or at least the DSCSA requirements (6 years).

A. Product Identification/Tracing Data

26. For each approved product (whether brand or generic) the FDA issues a unique 10-digit code (the National Drug Code, or NDC) that follows the product from manufacturing through retail dispensing. The NDC embeds details about the specific product, including the identity of the manufacturer (or labeler), the strength, dosage form, and formulation of the drug, and the package size and type.[15]

27. The NDC is a critical component of each and every transfer of a prescription drug (from the manufacturer to the wholesaler; from the wholesaler to the retailer; and from the retailer to the consumer) and therefore every transaction is accompanied by and labeled with the NDC. This same code is used by TPPs in the real-time claims adjudication process to identify the precise dollar amount they will reimburse the pharmacy for a particular prescription drug purchase. As far as I know, none of these basic facts is in dispute.

28. Retail prescription labels display the NDC of the dispensed product and this is part of the electronic dispensing record. In many cases, the Lot number will also appear on the prescription

[14] CVS Caremark, *Medicare Part D Compliance / Fraud, Waste & Abuse*, 2009, accessed March 12, 2020 at https://www.caremark.com/portal/asset/MedicarePartD.pdf, at p. 30.
[15] United States Food and Drug Administration, "National Drug Code Directory," accessed January 30, 2019 at https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm; FDA, "National Drug Codes Explained," accessed March 7, 2020 at https://www.drugs.com/ndc.html.

bottle provided to the consumer and, thus, specifically indicate whether the recall applies to the particular pills in the bottle.

29. However, even when not printed on the retail label, there are other methods available to pharmacies to link a dispensed product to a recalled Lot number. Harvard Medical School instructs consumers to call their pharmacy if their drug is the subject of a recall and the Lot number does not appear on their pill bottle.[16] GoodRx similarly states: "Pharmacies keep records of which lots they've used and when, so they'll be able to tell you if you have a recalled medication based on when your prescription was filled."[17] A September 2019 article in US Pharmacist Online discussing Angiotensin Receptor Blockers (such as VCDs) states: "If a patient is taking any medication that may be recalled, he or she should compare the information on the prescription bottle with the information in the FDA recall list (company, *National Drug Code, lot number*) to determine if current medicine has been recalled. If not certain, contact the pharmacist."[18] Insurance provider CIGNA Health instructs patients to "[p]lease check the label on your pill bottle to find out if your medication was recalled. Look for the information listed above [includes medication name, *lot number, NDC number*, and expiration date]. If everything matches, your medication was recalled. If it doesn't match, your medication wasn't recalled. If you need help finding this information, you can contact the pharmacy that filled your prescription."[19] AARP provides the following instructions: "You'll need the drug's name (generic and brand, if the drug has one), the

[16] Harvard Medical School Health Publishing, "What to do if your medication is recalled," May, 2019, accessed March 6, 2020 at https://www.health.harvard.edu/staying-healthy/what-to-do-if-your-medication-is-recalled.
[17] Lee, Benita, "Drug Recalls: 4 Steps to Take If You Have a Recalled Medication," *GoodRx*, February 13, 2019, accessed March 4, 2020 at https://www.goodrx.com/blog/drug-recalls-recalled-medication-what-to-do/#:~:text=Now%2C%20if%20you%20have%20a,out%20your%20drug's%20lot%20number.
[18] Terrie, Yvette C., "Overview of the FDA's Drug-Recall Process," September 17, 2019, *USPharmacist* 44, no. 9 (2019): 28-31, accessed March 6, 2020 at https://www.uspharmacist.com/article/overview-of-the-fdas-drugrecall-process (emphasis added).
[19] CIGNA Pharmacy Management, "Prescription Medication Recall," September 19, 2019, accessed March 6, 2020 at https://www.cigna.com/static/www-cigna-com/docs/individuals-families/rinitidine-hydrochloride-capsules-drug-recall.pdf (emphasis added).

dose, the manufacturer's name and the lot number to check against the FDA's recall list. You'll find some or all of that on the label. Hardest to find is the lot number; usually it is printed next to the expiration date, near the label's bar code or near the directions for use. On a drug blister pack, check the foil backing. For creams and gels, the lot number may be on the back of the tube. But the lot number and the manufacturer's name may be missing from the label entirely. In that case, your drugstore can provide the information."[20] According to the St. Joseph Candler Physician Network, "[e]very time you fill a prescription, the medication put in your hand is tracked by the pharmacy by the medicine's lot and expiration number. When recalls happen, the manufacturer contacts the pharmacy to identify the specific lot numbers involved in the drug recall."[21] In connection with one of the VCD recalls, Defendant CVS Caremark itself instructed consumers that "[t]his recall affects lot number 179791 exp. 03/31/20. To see if you received product, please check the lot number. The lot number is on the right-hand of the manufacturer's label or on the back of the tablet blister. If your product is not from this affected lot, it is not affected by this recall. If your product is from this affected lot, please contact the pharmacy that filled your prescription for more information including return instructions."[22]

30. Lot number is also used to report issues arising around a particular drug. For example, lot numbers are used by pharmacists to report Adverse Events (patient-specific side effects or complications associated with the use of a prescription drug). This is an important part of drug

[20] Harrar, Sari, "Tainted Drugs: Are Our Prescriptions Safe?" AARP, December 9, 2019, accessed March 6, 2020 at https://www.aarp.org/health/drugs-supplements/info-2019/drug-recall-what-to-do.html.
[21] St. Joseph's Candler, "What do I do if my medication is recalled?" October 9, 2019, accessed March 6, 2020 at https://www.sjchs.org/living-smart-blog/blog-details/blog/2019/10/09/what-do-i-do-if-my-medication-is-recalled
[22] CVS Caremark, "American Health Packaging Valsartan 160 mg Tablets Voluntary Recall," March 7, 2019, accessed March 6, 2020 at https://www.caremark.com/wps/portal/!ut/p/z1/04_Sj9CPykssy0xPLMnMz0vMAfIjo8ziHd3dgv09ggxDTQ0sjA08_cKcHY3CHI0MDAz0wwkpiMIvHUlIf0FuRCUAj08ApQ!!/?cms=CMS-PWCM-1114717.

safety monitoring in the United States and has led to recalls or relabeling of numerous drugs. Pharmacists make such reports using the FDA's MedWatch system using Form 3500.[23]

31. The production of data on the basis of NDCs or other objective criteria is facilitated and made feasible because data is typically electronically stored and contained within a structured database. In order to retrieve information from these structured databases, a query is used to define the parameters of the search. The query used to extract that data from a database can identify one or any number of NDCs in a single request. The process of querying such databases is not significantly more difficult or time consuming when the query involves multiples NDCs as opposed to just one. Extracting data from structured databases using queries is a standard part of the business operations of the pharmaceutical industry and is essential to performing drug utilization analyses, generic efficiency analyses, substitution studies and cost analyses in which all NDCs associated with the subject of interest are gathered simultaneously.

32. A key part of the DSCSA is the requirement that "product tracing information should be exchanged" for each transaction and retained for at least six years,[24] including the following transaction information ("TI"):[25]

- Proprietary or established name or names of the product
- Strength and dosage form of the product
- National Drug Code (NDC) number of the product
- Container size
- Number of containers
- **Lot number of the product**
- Date of the transaction

[23] FDA, "Instructions for Completing Form FDA 3500," accessed March 9, 2020 at https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500#Section%20B:%20Adverse%20Event%20or%20Product%20Problem.
[24] FDA, *Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act) Overview of Product Tracing Requirements*, September 2015, accessed March 4, 2020 at https://www.fda.gov/media/93779/download, at p. 8; FDA, *Protect Your Patients*, accessed February 25, 2020 at https://www.fda.gov/media/113114/download; DSCSA, Sections 582 (b)(1)(A)(ii), 582 (c)(bb)(BB)(II)(v)(I), 582 (d)(1)(A)(iii).
[25] FDA, *Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act) Overview of Product Tracing Requirements*, September 2015, accessed March 4, 2020 at https://www.fda.gov/media/93779/download, at pp. 8-9.

- Date of the shipment, if more than 24 hours after the date of the transaction
- Business name and address of the person from whom and to whom ownership is being transferred

33. I have been advised by Counsel that the Wholesaler Defendants have represented that they were "not required to pass on lot/batch information to retailers."

34. While it is true that primary wholesalers (those purchasing drugs directly from manufacturers with whom they have an established relationship) lobbied for and ultimately received an exemption from the tracing requirements on the basis that the documentation and labeling requirements would be too onerous for them, this narrow and limited exemption does not mean that Wholesalers have no lot or batch number for VCDs in their possession *at all*.

35. It is without dispute that primary Wholesalers receive and retain the Lot numbers on all product they obtain directly from drug manufacturers. For example, Cardinal Health states that it "tracks the inbound lot numbers of product received into [it's] distribution centers . . . ." However it says that it does not "track outbound lots shipped to customers for product purchased direct."[26]

36. Additionally, as it relates to downstream sales, because both wholesalers and retailers are required to create and maintain a wealth of electronic records (and are required to keep these records in such a way to respond to inquiry within 48 hours), this means that wholesalers have more than enough information in their inventory systems that could be used to associate lot numbers with their own sales.

37. For example, although manufacturer units (a bottle containing pills) are inarguably imprinted with Lot numbers for the reasons previously discussed, the DSCSA additionally

[26] CardinalHealth, *Drug Tracing – Frequently Asked Questions*, 2016, accessed March 4, 2020 at https://www.cardinalhealth.com/content/dam/corp/web/documents/brochure/CardinalHealth-DrugTracingFAQsCustomers.pdf, at p. 3.

mandates use of a composite "product identifier" that manufacturers were required to begin applying to prescription drug packages and cases.[27]

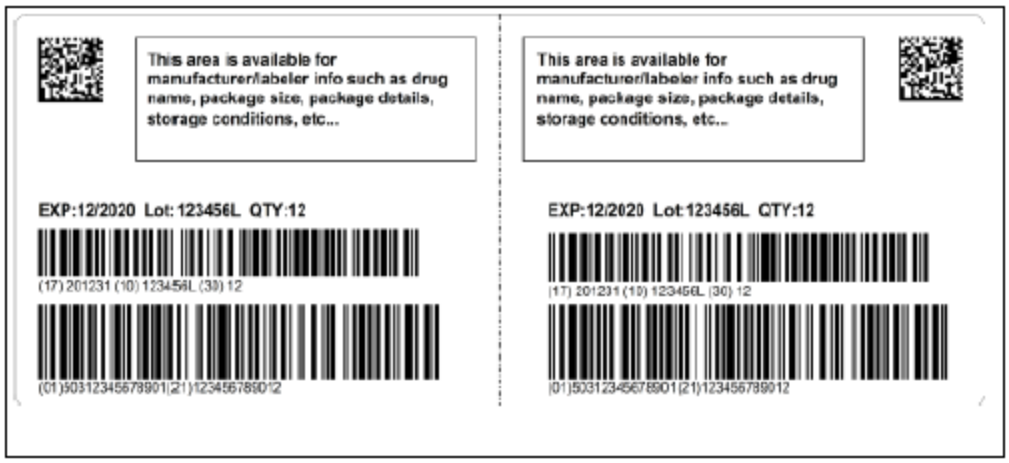
38. The term "product identifier" "means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier . . . , the standardized numerical identifier, lot number, and expiration date of the product."[28]

39. Publicly available Guidelines published by AmerisourceBergen require that "each Prescription Drug lowest saleable unit" it receives from a manufacturer must have the clearly indicated product identifier on the unit label.[29] In addition, case labels, and partial case labels must list the lot number and expiration date.[30] The Guidelines illustrate these requirements as reproduced in Figure 4.

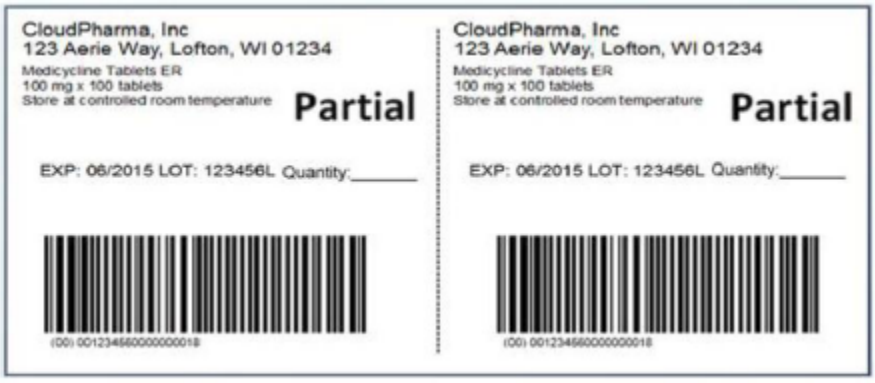
Figure 2. AmerisourceBergen Manufacturer Labeling Requirements[31]

DSCSA RX Serialized Unit Label

[27] Enforcement of this rule was delayed by the FDA until November 2018 (FDA, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry*, September 2018, accessed March 4, 2020 at https://www.fda.gov/media/106198/download, at p. 1).
[28] 21 U.S. Code §360eee(14).
[29] AmerisourceBergen, *AmerisourceBergen Manufacturer Packaging and Logistics Requirements Guide*, January 2019, accessed February 25, 2020 at https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-final-v14.pdf?la=en&hash=5297B4C716DBBE9A956F31CD2B194BD165F97465, at p. 14.
[30] AmerisourceBergen, *AmerisourceBergen Manufacturer Packaging and Logistics Requirements Guide*, January 2019, accessed February 25, 2020 at https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-final-v14.pdf?la=en&hash=5297B4C716DBBE9A956F31CD2B194BD165F97465, at pp. 15-16.
[31] AmerisourceBergen, *AmerisourceBergen Manufacturer Packaging and Logistics Requirements Guide*, January 2019, accessed February 25, 2020 at https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-final-v14.pdf?la=en&hash=5297B4C716DBBE9A956F31CD2B194BD165F97465, at pp. 14-16.



Example of Rx Serialized Homogenous Case Label



Example Partial Case Labeled with SSCC

40. Receiving all of this information in electronic format facilitates its entry into the Wholesaler inventory system. Because prescription drug products have a strictly limited shelf life and cannot properly be sold after their expiration, the inventory management process must, on an automated basis, be able to pick the oldest Lots of a given NDC as it fulfills orders each day. As a result, data from Amerisource Bergen and the other primary Wholesalers should reflect quantities of particular Lots or expiries removed from inventory and shipped each day.

41. Even prior to DSCSA, pharmaceutical industry stakeholders were making use of the EDI 856 - Advance Ship Notice (ASN), which provides detailed information about a pending delivery of goods. The ASN describes the contents that have been shipped as well as the carrier

moving the order, the size of the shipment, ship date and other product details. The ASN is typically sent from a product supplier to a retailer or distributor, but it can also be sent from a third-party logistics provider to a retailer or distributor. In the pharmaceutical setting, the largest retailers and wholesalers have their own guidelines regarding the implementation of ASN. The current versions of guidelines issued by CVS[32] (as a pharmacy) and Cardinal Health[33] (as a wholesaler) for example, are designed for compliance with the DSCSA transaction history and product identifier system. However, even a 2005 Walgreens ASN User Guide[34] reflected that Lot numbers were required to be inserted in the ASN for drug products being delivered to it.

42. The tracking of Lot numbers, whether through shipment labeling under the DSCSA, inventory control systems, or Advance Shipping Notices, is valuable for Wholesalers and Retailers alike, as each of them may be called upon to remove recalled product from their stock and doing so promptly makes it possible to return the product to the manufacturer and obtain a refund.

43. The FDA's General Industry Guidance regarding recalls provides that, in the event of a firm-initiated recall, the drug supply chain will be asked to provide information to the FDA, including "[t]otal amount of such products produced and/or the timespan of the production," "[t]otal amount of such products estimated to be in distribution channels," and "[d]istribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts."[35]

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[32] CVS, *856 Advance Ship Notice Supplier Implementation Guide*, May 2018, accessed March 10, 2020 at https://cvssuppliers.com/sites/default/files/CVSHealth%20856%20ASN%202018%201.7.pdf, at p. 2.
[33] Cardinal Health, *856 Advance Ship Notice Supplier Implementation Guide*, November 2015, accessed March 10, 2020 at https://www.cardinalhealth.com/content/dam/corp/web/documents/brochure/CardinalHealth-ASN856Guidelines.pdf, at p. 2.
[34] Walgreens, *Walgreens EDI 856 Advance Ship Notice User Guide*, October 2005, accessed March 10, 2020 at https://www.jobisez.com/edi-igs/Walgreens/856DC4010.pdf, at p. 26.
[35] 21 CFR §7.46 Firm-initiated recall.

44. These requirements to keep data in a sufficient form to recall product without large disruption is not new; rather, it simply codifies what large companies had already been doing to limit the costs associated with the business disruptions of recalls.

45. The FDA's General Industry Guidance also notes that "[a] recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect."[36] One of the steps is to "[u]se sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots."[37] The 2003 Federal Recall Guidelines similarly provide that a recall submission is to include product information such as the NDC, the lot/unit numbers and expiration dates, volume of recalled product, and distribution pattern which includes the number of direct accounts sold to.[38]

46. Given the reality that they keep, in the ordinary course of their business, a wealth of electronic tracking data (data that goes well beyond even the lot and batch number), Wholesalers are well poised to identify how best to link their sales shipments to recalled lots.

47. The above are non-exhaustive examples of the types of data that exist and can be used to identify which consumers and TPPs paid for which VCDs, and, more importantly, to apportion the market of VCDs by each manufacturer, wholesaler, and retail pharmacy, over time in an objective, administratively feasible manner. Absent access to these data, it would be significantly more time-consuming, expensive, and/or challenging to apportion the market of VCDs sold over time by each manufacturer, wholesaler and retail pharmacy.

[36] 21 CFR §7.59 General industry guidance.
[37] 21 CFR §7.59 General industry guidance.
[38] FDA, "Product Recalls, Including Removals and Corrections - Guidance for Industry," November 2003, accessed March 3, 2020 at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-recalls-including-removals-and-corrections.

B. Pricing Data

48. Both Wholesalers and Retailer Defendants have objected to producing financial information that they characterize as sensitive and burdensome to assemble. I understand from Counsel that one possible damage remedy in this case may include revenues received or profits earned by selling improperly manufactured or mislabeled VCDs.

49. Retailer revenue numbers are available from multiple sources. At the most granular level, they can be aggregated programmatically from the pharmacy log data by searching for sales associated with the relevant NDCs and limiting them to the dates when the relevant Lots were in stock (or simply at the NDC level if Lot level information is not required). Such databases can be searched programmatically using any number of NDCs. Sales price and dispensing fee earned will be reported for each transaction and can simply be summed. However, given the magnitude of these products, there may well be internal sales reports that already aggregate such figures. With regard to profits, these generally involve revenue generated, less the cost of the product to the pharmacy, less other variable costs. Defendant Retail Pharmacies have enormous purchasing power because of the large volume they require to satisfy their many stores. To maximize this power, purchasing is handled collectively with negotiated prices often being set formulaically based on a percentage discount from the manufacturer's Average Wholesale Price (effectively its "list" price). Electronic purchase data, purchasing schedules, or cost reports could all be used to determine the price paid for the VCDs. Any other costs to be considered can be identified and allocated from financial statements.

50. In short, there are many forms of data Defendants could supply to satisfy these discovery requests. Notably, much of the foregoing data is in the hands of Retail Pharmacy and Wholesaler Defendants themselves, not consumers or TPPs.

C. Product Returns

51. Pharmacies are expected to take a number of steps in the event of a drug recall, including removing any recalled product from their shelves. This product is normally collected in a specific location and bin for shipping back to the manufacturer and is entered in an electronic system used specifically for processing such returns. Consumers may also bring product back to the pharmacy where they purchased it when they learn of a recall. The consumer may or may not receive a refund for the returned product. Information related to consumer returns, in the aggregate, should be available in the same pharmacy log system that contains records of prescriptions dispensed and payments received.

I declare under penalty of perjury that the foregoing is true and correct. Executed in [redacted] [redacted] the 12th day of March 2020.

[redacted]